

115TH CONGRESS  
1ST SESSION

# H. R. 2194

To protect the public health by providing the Food and Drug Administration with certain authority to regulate e-liquids and personal electronic vaporizers, to reduce the morbidity and mortality resulting from cigarette smoking through the responsible regulation of e-liquids and personal electronic vaporizers as a tobacco harm reduction strategy, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

APRIL 27, 2017

Mr. HUNTER introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To protect the public health by providing the Food and Drug Administration with certain authority to regulate e-liquids and personal electronic vaporizers, to reduce the morbidity and mortality resulting from cigarette smoking through the responsible regulation of e-liquids and personal electronic vaporizers as a tobacco harm reduction strategy, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2       (a) SHORT TITLE.—This Act may be cited as the  
3       “Cigarette Smoking Reduction and Electronic Vapor Al-  
4       ternatives Act of 2017”.

5       (b) TABLE OF CONTENTS.—The table of contents of  
6       this Act is as follows:

See. 1. Short title; table of contents.

See. 2. Findings.

See. 3. Purposes of the Family Smoking Prevention and Tobacco Control Act.

See. 4. Regulation of electronic vapor products.

See. 5. Joint comparative health risk assessment.

7 **SEC. 2. FINDINGS.**

8       The Congress finds the following:

9           (1) Cigarette smoking is the practice of burning  
10          tobacco rolled in a paper and inhaling the smoke.  
11          According to the Department of Health and Human  
12          Services—

13              (A) the burning of tobacco produces a  
14          chemical mixture of more than 7,000 com-  
15          pounds;

16              (B) cigarette smoking causes cancer, heart  
17          disease, stroke, lung diseases, diabetes, and  
18          chronic obstructive pulmonary disease, and  
19          harms nearly every organ of the body;

20              (C) cigarette smoking causes more than  
21          480,000 deaths each year, including nearly  
22          42,000 deaths due to secondhand tobacco  
23          smoke;

1                             (D) the economic cost of cigarette smoking  
2                             is more than \$300 billion a year, including  
3                             nearly \$170 billion in direct medical care, and  
4                             more than \$156 billion in lost productivity; and  
5                             (E) nearly 7 in 10 adult cigarette smokers  
6                             want to quit smoking.

7                             (2) Electronic vapor products, also known as  
8                             “electronic cigarettes” or “e-cigarettes”, are battery-  
9                             operated devices that use low heat to turn e-liquid,  
10                            which generally contains nicotine, into a vaporized  
11                            aerosol which is inhaled—there is no burning of to-  
12                            bacco or generation of smoke for inhalation.

13                            (3) Evidence from numerous studies strongly  
14                            suggests that electronic vapor products are mag-  
15                            nitudes safer than traditional, combustible ciga-  
16                            rettes. Studies have found that several million reg-  
17                            ular vapers in the United States no longer regularly  
18                            smoke cigarettes.

19                            (4) Studies of cigarette smokers who switched  
20                            to vapor found significant improvements in lung  
21                            function, including a study finding asthmatic smok-  
22                            ers who switched to vapor had significant improve-  
23                            ments in spirometry data, asthma control, airway  
24                            hyperresponsiveness, and lower blood pressure.

1                             (5) The Royal College of Physicians 2016 re-  
2 port on e-cigarettes titled, “Nicotine without smoke:  
3 Tobacco harm reduction” issued the following find-  
4 ings:

5                             (A) The available evidence to date indi-  
6 cates that e-cigarettes are being used almost ex-  
7 clusively as safer alternatives to smoked to-  
8 bacco, by confirmed smokers who are trying to  
9 reduce harm to themselves or others from  
10 smoking, or to quit smoking completely.

11                            (B) The hazard to health arising from  
12 long-term vapor inhalation from the e-cigarettes  
13 available today is unlikely to exceed 5 percent  
14 of the harm from smoking tobacco.

15                            (C) E-cigarettes are marketed as consumer  
16 products and are proving much more popular  
17 than Food and Drug Administration-approved  
18 nicotine replacement therapies (NRT) as a sub-  
19 stitute and competitor for tobacco cigarettes.

20                            (6) “E-liquid” is the liquid that is heated into  
21 vapor. It contains, principally, propylene glycol, veg-  
22 etable glycerin, in some cases food flavoring, in some  
23 cases nicotine, and in some cases water; propylene  
24 glycol and vegetable glycerin are designated as “gen-

1       erally recognized as safe” by the Food and Drug Ad-  
2       ministration (FDA) as food additives.

3           (7) Surveys have found that a significant ma-  
4       jority of regular users of electronic vapor products  
5       had previously tried FDA-approved smoking ces-  
6       sation drugs to quit smoking without success.

7           (8) An expert independent evidence review pub-  
8       lished by Public Health England (PHE) concluded  
9       that—

10           (A) the use of vapor products is about 95  
11       percent less harmful than cigarette smoking;

12           (B) nearly half the population doesn’t real-  
13       ize vapor is much less harmful than smoking;  
14       and

15           (C) there is no evidence suggesting elec-  
16       tronic vapor products act as a route into smok-  
17       ing for children or nonsmokers.

18           (9) Electronic vapor product sales in the United  
19       States have increased from an estimated \$100 mil-  
20       lion in 2010 to \$4 billion in 2016 while cigarette  
21       consumption in the United States declined from  
22       \$307 billion in 2010 to an estimated \$265 billion in  
23       2016.

24           (10) On May 10, 2016, the Food and Drug Ad-  
25       ministration issued its “Deeming Regulation” to

1       deem e-cigarettes or electronic vapor products to be  
2       subject to its authority. The regulation will, as a  
3       practical matter, because of its significant compli-  
4       ance costs and poorly articulated standard for pro-  
5       tecting public health, ban the sale of all electronic  
6       vapor products by August 2018.

7                 (11) The Food and Drug Administration's  
8       Deeming Regulation, by effectively banning elec-  
9       tronic vapor products, will push vapers who have  
10      quit or reduced cigarette smoking by switching to  
11      electronic vapor products back to smoking deadly  
12      cigarettes.

13                 (12) The 2015 Monitoring the Future survey of  
14       the National Institute on Drug Abuse found past-  
15       30-day use of an electronic vapor product by 8th,  
16       10th, and 12th graders combined declined from 13.9  
17       percent in 2014 to 9.9 percent in 2016; however,  
18       that survey found that fewer than 20 percent of  
19       teens who used an electronic vapor product in the  
20       past 30 days reported using a product containing  
21       nicotine.

22                 (13) Electronic vapor products show tremen-  
23       dous promise in reducing cigarette smoking, and cig-  
24       arette smoking attributable morbidity, mortality,  
25       and health care costs.

1                                 (14) According to an April 13, 2017, Centers  
2                                 for Disease Control and Prevention study, more  
3                                 Americans who are trying to quit smoking use vapor  
4                                 products (35.3 percent) than any other smoking ces-  
5                                 sation tool. This includes using a nicotine patch or  
6                                 gum (25.4 percent), getting help from a doctor or  
7                                 other health professional (15.2 percent), using smok-  
8                                 ing cessation medications approved by the Food and  
9                                 Drug Administration (12.2 percent), and getting  
10                                 help from a website (7.1 percent) or a telephone  
11                                 quitline (5.4 percent).

12                                 (15) Since the Food and Drug Administration  
13                                 was granted authority to regulate tobacco products  
14                                 in 2009, the agency has failed to grant market ap-  
15                                 proval to any modified risk tobacco product.

16                                 **SEC. 3. PURPOSES OF THE FAMILY SMOKING PREVENTION  
17   AND TOBACCO CONTROL ACT.**

18                                 Section 3 of the Family Smoking Prevention and To-  
19                                 bacco Control Act (21 U.S.C. 387 note) is amended by  
20                                 amending paragraph (9) to read as follows:

21                                 “(9) to promote—

22                                 “(A) cessation to reduce disease risk and  
23                                 the social costs associated with tobacco-related  
24                                 diseases; and

25                                 “(B) harm reduction strategies; and”.

1     **SEC. 4. REGULATION OF ELECTRONIC VAPOR PRODUCTS.**

2         (a) CENTER FOR TOBACCO PRODUCTS AND TOBACCO  
3     HARM REDUCTION.—Section 901(e) of the Federal Food,  
4     Drug, and Cosmetic Act (21 U.S.C. 387a(e)) is amend-  
5     ed—

6             (1) in the subsection heading, by striking  
7     “CENTER FOR TOBACCO PRODUCTS” and inserting  
8     “CENTER FOR TOBACCO PRODUCTS AND TOBACCO  
9     HARM REDUCTION”;

10            (2) by striking “Center for Tobacco Products”  
11     and inserting “Center for Tobacco Products and To-  
12     bacco Harm Reduction”; and

13            (3) by striking “this chapter” and inserting  
14     “this chapter and chapter X”.

15         (b) FDA AUTHORITY OVER ELECTRONIC VAPOR  
16     PRODUCTS.—

17            (1) EXCLUSION FROM DEFINITION OF TOBACCO  
18     PRODUCT.—Section 201(rr) of the Federal Food,  
19     Drug, and Cosmetic Act (21 U.S.C. 321(rr)) is  
20     amended—

21              (A) in paragraph (2), by inserting “an e-  
22     liquid (as defined in section 1001), a personal  
23     electronic vaporizer (as defined in section  
24     1001),” before “or a combination product”; and

25              (B) in paragraph (3), by inserting after  
26     “The products described in paragraph (2)” the

1           following: “(other than an e-liquid or personal  
2           electronic vaporizer)”.  
3

4           (2) COMBINATION PRODUCTS.—Section 503(g)  
5           of the Federal Food, Drug, and Cosmetic Act (21  
6           U.S.C. 353(g)) is amended—  
7

8               (A) in paragraph (1)—  
9

10                 (i) in subparagraph (A), by striking  
11                 “or biological product” and inserting “, bi-  
12                 ological product, e-liquid, or personal elec-  
13                 tronic vaporizer”; and  
14

15                 (ii) in subparagraph (D)—  
16

17                         (I) in clause (ii), by striking “or”  
18                         at the end;  
19

20                         (II) in clause (iii), by striking the  
21                         period at the end and inserting “; or”;  
22                         and  
23

24                         (III) by adding at the end the  
25                         following:  
26

27                         “(iv) an e-liquid or personal electronic vapor-  
28                         izer, the agency center charged with regulating e-liq-  
29                         uids and personal electronic vaporizers shall have  
30                         primary jurisdiction.”; and  
31

32                 (B) in paragraph (9)—  
33

1                             (i) by redesignating subparagraphs  
2                             (C) and (D) as subparagraphs (D) and  
3                             (E), respectively; and

4                             (ii) by inserting after subparagraph  
5                             (B) the following:

6                             “(C) The terms ‘e-liquid’ and ‘personal elec-  
7                             tronic vaporizer’ have the meanings given to such  
8                             terms in section 1001.”.

9                             (3) REGULATORY AUTHORITY.—The Federal  
10                             Food, Drug, and Cosmetic Act (21 U.S.C. 301 et  
11                             seq.) is amended—

12                             (A) by redesignating chapter X as chapter  
13                             XI;

14                             (B) by redesignating sections 1001  
15                             through 1014 as sections 1101 through 1114,  
16                             respectively;

17                             (C) in section 505(n)(2), by striking  
18                             “1004” and inserting “1104”;

19                             (D) in sections 523(b)(2)(D) and  
20                             704(g)(13), by striking “1003(g)” and inserting  
21                             “1103(g)”;

22                             (E) in section 1109(a)(5)(A), as redesi-  
23                             gnated by paragraph (4), by striking “1008”  
24                             and inserting “1108”; and

1                         (F) by inserting after chapter IX the fol-  
2                         lowing:

3                         **“CHAPTER X—ELECTRONIC VAPOR  
4                         PRODUCTS**

5                         **“SEC. 1001. DEFINITIONS.**

6                         “In this chapter:

7                         “(1) The term ‘e-liquid’ means any liquid solu-  
8                         tion that—

9                         “(A) may or may not contain nicotine; and  
10                         “(B) is intended to be converted into an  
11                         aerosol, vapor, or vapor-like mist for users to  
12                         inhale through the mouthpiece of a personal  
13                         electronic vaporizer.

14                         “(2) The term ‘personal electronic vaporizer’  
15                         means an electronic device that employs a heating  
16                         element or atomizer that converts an e-liquid into an  
17                         aerosol, vapor, or vapor-like mist through a non-  
18                         combustive process.

19                         “(3) The terms ‘e-liquid’ and ‘personal elec-  
20                         tronic vaporizer’ exclude—

21                         “(A) a drug as defined in section  
22                         201(g)(1);

23                         “(B) a device as defined in section 201(h);  
24                         and

1               “(C) a biological product as defined in sec-  
2               tion 351 of the Public Health Service Act.

3   **“SEC. 1002. EXCLUSIVE AUTHORITY FOR REGULATING E-**  
4               **LIQUIDS AND PERSONAL ELECTRONIC VA-**  
5               **PORIZERS.**

6               “The authorities vested by this chapter constitute the  
7               exclusive authorities of the Secretary to regulate e-liquids  
8               and personal electronic vaporizers, except to the extent e-  
9               liquids and personal electronic vaporizers are within com-  
10              bination products regulated pursuant to section 503(g).

11   **“SEC. 1003. PROHIBITED ACTS; PENALTIES.**

12              “(a) PROHIBITIONS.—

13              “(1) IN GENERAL.—The following acts and the  
14              causing thereof are hereby prohibited:

15              “(A) The sale of an electronic vapor prod-  
16              uct or e-liquid to any person younger than 18  
17              years of age.

18              “(B) The manufacture of an e-liquid or  
19              personal electronic vaporizer in noncompliance  
20              with the standards under section 1004(b) in  
21              violation of an order issued under section  
22              1004(e).

23              “(C) The offering of e-liquids or personal  
24              electronic vaporizers for sale in interstate com-  
25              merce by an e-liquid or personal electronic va-

1 porizer manufacturer that does not have a cer-  
2 tification in effect as required by section  
3 1004(c).

4 “(D) The failure by an e-liquid or personal  
5 electronic vaporizer manufacturer to provide ac-  
6 cess for inspection as required by section  
7 1004(d).

8 “(E) The introduction or delivery for intro-  
9 duction in interstate commerce of an e-liquid or  
10 personal electronic vaporizer by any person that  
11 is adulterated or misbranded, as described in  
12 subsection (b) or (c) respectively.

13 “(2) RETAILERS.—Notwithstanding subpara-  
14 graphs (A) and (E) of paragraph (1), a retailer may  
15 be found to be in violation of either such subpara-  
16 graph (with respect to sale or introduction or deliv-  
17 ery for introduction in interstate commerce at retail)  
18 only if the violation occurs knowingly.

19 “(b) ADULTERATION.—An e-liquid or personal elec-  
20 tronic vaporizer shall be treated as adulterated if—

21 “(1) it was manufactured in noncompliance  
22 with the standards under section 1004(b) in viola-  
23 tion of an order issued under section 1004(e); or

24 “(2) it was manufactured by an e-liquid or per-  
25 sonal electronic vaporizer manufacturer that does

1       not have a certification in effect as required by sec-  
2       tion 1004(c).

3       “(c) MISBRANDING.—An e-liquid or personal elec-  
4       tronic vaporizer shall be treated as misbranded if its label-  
5       ing (as such term is defined in section 201 with respect  
6       to drugs) is in noncompliance with the standards under  
7       section 1004(b) in violation of an order issued under sec-  
8       tion 1004(e).

9       “(d) PENALTIES.—Any person who violates a provi-  
10      sion of subsection (a) shall be imprisoned not more than  
11      3 years, fined not more than \$10,000 (notwithstanding  
12      section 3571(e) of title 18, United States Code) for each  
13      day on which the violation continues, or both.

14      **“SEC. 1004. STANDARDS FOR THE MANUFACTURING OF E-**  
15                   **LIQUIDS AND PERSONAL ELECTRONIC VA-**  
16                   **PORIZERS; COMPLIANCE.**

17       “(a) REQUIREMENT.—Beginning on the date that is  
18      1 year after the date of enactment of the Cigarette Smok-  
19      ing Reduction and Electronic Vapor Alternatives Act of  
20      2017, any e-liquid or personal electronic vaporizer intro-  
21      duced or delivered for introduction into interstate com-  
22      merce shall conform to the e-liquid or personal electronic  
23      vaporizer (as applicable) manufacturing standards under  
24      subsection (b), including the labeling standards therein.

25       “(b) MANUFACTURING STANDARDS.—

1           “(1) E-LIQUIDS.—The manufacturing stand-  
2       ards for e-liquids under this subsection shall consist  
3       of the following:

4           “(A) INTERIM STANDARDS.—The e-liquid  
5       manufacturing standards issued by the Amer-  
6       ican E-Liquid Manufacturing Standards Asso-  
7       ciation (version 2.3.2) on March 8, 2017 (in-  
8       cluding any revision to such standards made in  
9       accordance with paragraph (3)), apply to the  
10      introduction or delivery for introduction into  
11      interstate commerce of e-liquids during the pe-  
12      riod beginning on the date described in sub-  
13      section (a) and ending on the date described in  
14      subparagraph (B).

15           “(B) SUBSEQUENT STANDARDS.—The e-  
16       liquid manufacturing standards of the American  
17       National Standards Institute (including any re-  
18       vision to such standards made in accordance  
19       with paragraph (3)) apply to the introduction  
20       or delivery for introduction into interstate com-  
21       merce of e-liquids beginning on the date of the  
22       adoption of such standards by the American  
23       National Standards Institute.

24           “(2) PERSONAL ELECTRONIC VAPORIZERS.—  
25       The manufacturing standards for personal electronic

1 vaporizers under this subsection shall consist of the  
2 following:

3           “(A) BATTERY SAFETY.—Any battery used  
4           in a personal electronic vaporizer shall conform  
5           to the IEC 62133 standards of the Interna-  
6           tional Electrotechnical Commission, as in ef-  
7           fect on the date of enactment of the Cigarette  
8           Smoking Reduction and Electronic Vapor Alter-  
9           natives Act of 2017 and including any revision  
10          to such standards made in accordance with  
11          paragraph (3).

12           “(B) SHORT CIRCUIT PROTECTION.—A  
13          personal electronic vaporizer shall have a mech-  
14          anism to ensure user and battery safety in the  
15          event of a short circuit of the heating element.

16           “(C) DISCHARGE MONITORING.—A re-  
17          chargeable personal electronic vaporizer shall  
18          have a mechanism to prevent the battery from  
19          being discharged below a safe voltage during  
20          use or discharged faster than the battery can  
21          sustain safely.

22           “(D) CHARGE MONITORING.—A personal  
23          electronic vaporizer that contains an onboard  
24          charger shall include circuitry to monitor the  
25          battery voltage and charge current and limit

1           these to safe levels. A personal electronic vapor-  
2           izer that contains multiple battery cells in series  
3           shall monitor the cells individually.

4           “(E) SERIAL AND LOT NUMBERS.—A per-  
5           sonal electronic vaporizer shall include a serial  
6           or lot number on the label that allows the va-  
7           porizer to be traced to its time and place of  
8           manufacture. Notwithstanding the preceding  
9           sentence, a single-use personal electronic vapor-  
10          izer may have such serial or lot number on the  
11          packaging of the vaporizer other than the label.

12          “(F) VERIFICATION AND VALIDATION.—A  
13          personal electronic vaporizer shall be con-  
14          structed with sufficiently validated processes, or  
15          subject to sufficient verification and testing, to  
16          ensure that each individual vaporizer conforms  
17          to its specifications.

18          “(G) TRACKING AND RECALLS.—The man-  
19          ufacturer of a personal electronic vaporizer  
20          shall record all shipments of one or more per-  
21          sonal electronic vaporizers by the manufacturer  
22          to a distributor, retailer, or end user, and cor-  
23          relate each such shipment to serial or lot num-  
24          bers, to enable batch tracking and recalls.

1                 “(H) MATERIALS.—The manufacturer of a  
2                 personal electronic vaporizer shall ensure that—

3                         “(i) materials that come in contact  
4                 with e-liquids or vapor during manufacture  
5                 or reasonably foreseeable use of the per-  
6                 sonal electronic vaporizer are limited to ap-  
7                 proved medical or food contact grade prod-  
8                 ucts with established safety and biocompat-  
9                 ability characteristics; and

10                         “(ii) components of a personal elec-  
11                 tronic vaporizer which are expected to be  
12                 subject to heat are appropriate for the ex-  
13                 pected temperatures.

14                 “(3) REVISIONS.—Before issuing a revision to  
15                 the standards applicable under paragraph (1)(A),  
16                 (1)(B), or (2)(A), the American E-Liquid Manufac-  
17                 turing Standards Association, the American Na-  
18                 tional Standards Institute, or the International Elec-  
19                 trotechnical Commission, as applicable, shall notify  
20                 the Secretary in writing of the proposed revision.  
21                 Not later than 90 days after the date of receipt of  
22                 such notice, the Secretary shall determine whether  
23                 the proposed revision enhances the safety and qual-  
24                 ity of e-liquid products or personal electronic vapor-  
25                 izers, as applicable. If the Secretary determines that

1       the proposed revision does enhance the safety and  
2       quality of e-liquid products or personal electronic va-  
3       porizers, as applicable, the Secretary shall give no-  
4       tice of such determination to the public for a period  
5       of 90 days and, effective at the end of such period,  
6       incorporate the revision into the standards applicable  
7       under paragraph (1)(A), (1)(B), or (2)(A), as appli-  
8       cable.

9       “(c) CERTIFICATION OF COMPLIANCE WITH MANU-  
10      FACTURING STANDARDS.—Beginning not later than 1  
11      year after the date of enactment of the Cigarette Smoking  
12      Reduction and Electronic Vapor Alternatives Act of 2017,  
13      each e-liquid and personal electronic vaporizer manufac-  
14      turer offering e-liquids for sale in interstate commerce  
15      shall have in effect a certification filed with the Secretary  
16      in writing that all such e-liquids or personal electronic va-  
17      porizers, as applicable, are manufactured, labeled, and  
18      otherwise in compliance with the standards under sub-  
19      section (b).

20       “(d) INSPECTIONS FOR COMPLIANCE WITH MANU-  
21      FACTURING STANDARDS.—E-liquid and personal elec-  
22      tronic vaporizer manufacturers shall provide the Secretary  
23      with access to their facilities used in manufacturing e-liq-  
24      uids or personal electronic vaporizers, as applicable, for  
25      inspection.

1       “(e) FAILURE TO COMPLY WITH MANUFACTURING  
2 STANDARDS.—

3           “(1) IN GENERAL.—If the Secretary finds that  
4 an e-liquid or personal electronic vaporizer manufac-  
5 turer is in noncompliance with the standards under  
6 subsection (b)—

7           “(A) the Secretary shall not take any en-  
8 forcement action based on such noncompliance  
9 unless—

10           “(i) the Secretary gives the manufac-  
11 turer notice of, and a period of 90 days to  
12 correct, such noncompliance; and

13           “(ii) the manufacturer fails, by the  
14 end of such 90-day period, to correct such  
15 noncompliance; and

16           “(B) if the manufacturer fails to correct  
17 such noncompliance, as described in paragraph  
18 (1)(A)(ii), the Secretary may issue an order re-  
19 quiring the manufacturer—

20           “(i) to suspend any commercial activ-  
21 ity that the Secretary finds to be in non-  
22 compliance; and

23           “(ii) to not resume such activity until  
24 the manufacturer demonstrates to the Sec-

1                           retary's satisfaction that such noncompli-  
2                           ance has been corrected.

3                 “(2) IMMEDIATE DANGER TO PUBLIC  
4                           HEALTH.—Notwithstanding paragraph (1), if the  
5                           Secretary determines that an e-liquid or personal  
6                           electronic vaporizer manufacturer is in noncompli-  
7                           ance with the standards under subsection (b), and  
8                           that such noncompliance presents an immediate dan-  
9                           ger to public health, the Secretary may issue an  
10                          order requiring the manufacturer to suspend produc-  
11                          tion of such e-liquid or personal electronic vaporizer  
12                          until the Secretary determines that such noncompli-  
13                          ance is corrected.

14 **“SEC. 1005. PROHIBITION AGAINST ADVERTISING OR PRO-**  
15                           **MOTING TO MINORS.**

16                 “(a) PROHIBITION.—The Secretary may by regula-  
17                          tion prohibit any manufacturer of an e-liquid or personal  
18                          electronic vaporizer from advertising or promoting the e-  
19                          liquid or personal electronic vaporizer to individuals who  
20                          have not attained 18 years of age.

21                 “(b) PENALTY.—If a manufacturer violates a prohi-  
22                          bition established under subsection (a), the Secretary may  
23                          refuse to accept for filing or renewal, and may revoke, the  
24                          manufacturer's certification under section 1004(c).

1     **“SEC. 1006. PREEMPTION OF CERTAIN STATE AND LOCAL**

2                 **REQUIREMENTS.**

3                 “(a) IN GENERAL.—No State or political subdivision  
4     of a State may establish or continue in effect any require-  
5     ment with respect to the manufacture, warning require-  
6     ments, marketing, distribution, or sale of an e-liquid or  
7     personal electronic vaporizer which is different from, or  
8     in addition to, any requirement under the provisions of  
9     this chapter or pursuant to section 503(g), including the  
10    exclusion of e-liquids and personal electronic vaporizers  
11    from the definition of a tobacco product under section  
12    201.

13                 “(b) EXCEPTION.—Information disclosed to a State  
14    consistent with subsection (a) that is exempt from disclo-  
15    sure under section 552(b)(4) of title 5, United States  
16    Code, shall be treated as a trade secret and confidential  
17    information by the State.

18     **“SEC. 1007. OFFICE FOR E-LIQUID AND PERSONAL ELEC-**

19                 **TRONIC VAPORIZER STANDARDS COMPLI-**  
20                 **ANCE.**

21                 “Not later than 90 days after the date of enactment  
22    of the Cigarette Smoking Reduction and Electronic Vapor  
23    Alternatives Act of 2017, the Secretary shall establish  
24    within the Food and Drug Administration’s Center for To-  
25    bacco Products and Tobacco Harm Reduction an Office

1 of E-Liquid and Personal Electronic Vaporizer Standards

2 Compliance. The Office shall—

3           “(1) be responsible for the implementation of  
4           this chapter and related matters assigned by the Di-  
5           rector of such Center; and

6           “(2) provide technical and other nonfinancial  
7           assistance to e-liquid and personal electronic vapor-  
8           izer manufacturers to assist them in complying with  
9           the requirements of this Act.”.

10 **SEC. 5. JOINT COMPARATIVE HEALTH RISK ASSESSMENT.**

11       Chapter X of the Federal Food, Drug, and Cosmetic  
12 Act, as added by section 4, is further amended by adding  
13 at the end the following:

14 **“SEC. 1008. TOBACCO PRODUCTS AND NICOTINE DELIVERY**  
15           **ALTERNATIVES: COMPARATIVE HEALTH RISK**  
16           **ASSESSMENT.**

17       “(a) ASSESSMENT.—The Secretary shall undertake a  
18 tobacco products and other nicotine delivery alternatives  
19 comparative health risk assessment and rank each cat-  
20 egory of products on a scale according to the reasonable  
21 expectation for morbidity and mortality risk when com-  
22 pared to smoking cigarettes based on laboratory studies  
23 and existing scientific data. For purposes of such assess-  
24 ment, tobacco and nicotine delivery alternative product  
25 categories shall include at a minimum—

1           “(1) cigarettes;

2           “(2) loose tobacco for roll-your-own tobacco

3           products;

4           “(3) little cigars;

5           “(4) cigars;

6           “(5) pipe tobacco;

7           “(6) moist snuff;

8           “(7) dry snuff;

9           “(8) chewing tobacco;

10          “(9) snus;

11          “(10) vaporized tobacco, meaning ‘heat not

12          burn’ technology intended for inhalation;

13          “(11) vapor produced by a personalized elec-

14          tronic vaporizer containing e-liquid with nicotine;

15          “(12) shisha and other tobacco products that

16          are heated and inhaled via a hookah, water pipe, or

17          other type of pipe (treated collectively as a single

18          category);

19          “(13) dissolvable, chewable, drinkable, and

20          other tobacco and nicotine products intended for oral

21          ingestion (treated collectively as a single category);

22          “(14) tobacco and nicotine skin creams, patch-

23          es, and other tobacco and nicotine products intended

24          for transdermal consumption (treated collectively as

25          a single category);

1           “(15) tobacco and nicotine sprays, droplets, and  
2        mists intended for nasal consumption (treated as a  
3        single category); and

4           “(16) other nicotine-containing products (treat-  
5        ed collectively as a single category).

6        “(b) REPORT.—Not later than 18 months after the  
7        date of enactment of the Cigarette Smoking Reduction  
8        and Electronic Vapor Alternatives Act of 2017, the Sec-  
9        retary shall report to the Committee on Energy and Com-  
10      merce of the House of Representatives and the Committee  
11      on Health, Education, Labor, and Pensions of the Senate  
12      on the results of the comparative health risk assessment  
13      under subsection (a). Based on such results, such report  
14      shall include recommendations on—

15           “(1) new or improved tobacco harm reduction  
16        strategies; and

17           “(2) the possible need for additional legislative  
18        authorities to implement such strategies.”.

